UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

TONYA MARGOWSKI, Plaintiff, v. BOSTON SCIENTIFIC CORP. Defendant.	Court File No.: 0:22-cv-128 **COMPLAINT** **DEMAND FOR JURY TRIAL**

TO: ABOVE NAMED DEFENDANT AND THEIR ATTORNEYS

Plaintiff, by and through counsel, allege on personal knowledge as to herself, and on information and belief as to all other matters, as follows against Defendant Boston Scientific Corporation (hereinafter "Boston Scientific" or "BSC"):

I. NATURE OF THESE ACTIONS

1. Plaintiff seeks compensation for injuries resulting from use of Defendant's Obtryx System - Halo Transobturator Mid-Urethral Sling System; ("Obtryx Halo" or "Obtryx Halo sling"), which Defendants designed, manufactured, marketed, distributed, packaged, and sold to treat stress urinary incontinence (SUI) in women.

II. PLAINTIFF

2. Plaintiff Tonya Margowski is and was at all relevant times a resident of Itasca County, Minnesota.

III. DEFENDANT

3. Defendant Boston Scientific Corp. is and was at all relevant times a Delaware Corporation with its principal place of business located at 300 Boston Scientific Way, Marlborough, Massachusetts 01752.

4. At all relevant times herein mentioned, Defendant Boston Scientific conducted regular and sustained business in Minnesota by marketing, distributing and selling its products in Minnesota. Boston Scientific also has two manufacturing facilities in the State of Minnesota, located in Arden Hills and in Maple Grove. All acts and omissions of Boston Scientific as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownerships.

5. The product known as the Obtryx System -Halo Transobturator Mid-Urethral Sling System; ("Obtryx Halo" or "Obtryx Halo sling"), as well as any variations of this product and any unnamed BSC Pelvic Mesh Products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation and the Pelvic Mesh Products designed and sold for similar purposes by the Defendant listed below, are collectively referenced herein as "Defendant's Pelvic Mesh Products" or "the Products."

6. The Defendant had a legal duty to ensure the safety and effectiveness of its Pelvic Mesh Products by conducting adequate and well-controlled studies on its Products prior to marketing. The Defendant deliberately chose to manipulate the only studies that were conducted on their Products, and by so doing, provided doctors and patients with false and misleading information about the safety and effectiveness of its Pelvic Mesh Products. Furthermore, the Defendant made a conscious decision to forego performing studies and creating registries that would have provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of the Pelvic Mesh Products.

7. At all times material to this action, Defendant has designed, patented, manufactured, labeled, marketed, and sold and distributed a line of Pelvic Mesh Products. These Products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ

prolapse. These Products share common design elements and common defects. Additionally, each of these Products were cleared for sale in the U.S. after the Defendant made assertions to the Food and Drug Administration ("FDA") of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

8. At all times alleged herein, the Defendant includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

IV. JURISDICTION AND VENUE

9. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship between Plaintiff and the Defendant, and because Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs.

10. Venue is proper as Plaintiff was implanted with the defective device and was injured in and received treatment in the State of Minnesota.

V. PRE-SUIT NOTICE

11. On or about December 11 2020, Plaintiff provided Defendant with pre-suit notice. Defendant acknowledged receipt of this notice on December 18, 2020. Plaintiff supplemented this with an additional letter on December 21, 2020.

12. Prior to filing this Complaint Plaintiff also provided Defendant with full copies of Ms. Margowski's medical records, which provide Defendant with exhaustive detail regarding the use of the Obtryx sling, implanting surgery and resulting injuries.

VI. RELEVANT FACTS

13. Boston Scientific's Obtryx Halo System is a mid-urethral mesh sling "intended for use as a suburethral sling for the treatment of stress incontinence resulting from hypermobility and/or intrinsic sphincter deficiency."

14. Boston Scientific designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed Obtryx Halo sling products, which are delineated below. These products were designed primarily for the purposes of treating stress urinary incontinence.

15. At all material times hereto, Defendant engaged in the developing, inspecting, testing, assembling, designing, licensing, labeling, manufacturing, distributing, packaging, supplying, marketing, advertising, and/or selling, either directly or indirectly through third parties or related entities, transvaginal placed mesh devices for the treatment of incontinence and pelvic organ prolapse.

16. The Defendant knew, or should have known, that the transvaginal placed mesh devices were defective and not safe and/or effective as originally developed, inspected, tested, assembled, designed, licensed, labeled, manufactured, distributed, packaged, supplied, marketed, advertised and/or sold.

17. Many of Defendant's Pelvic Mesh Products, including the Obtryx Halo sling, contain non-absorbable synthetic, monofilament polypropylene mesh. Despite claims that polypropylene is inert, the scientific evidence shows that this material, as implanted in Tonya Margowski, is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with Defendant's Pelvic Mesh Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

18. Furthermore, Defendant's Pelvic Mesh Products, including the Obtryx Halo sling, cause hyper-inflammatory responses leading to problems including chronic pain and fibrosis. Defendant's polypropylene Pelvic Mesh Products disintegrate after implantation in the female pelvis. They harden in the body. When polypropylene mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

19. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Boston Scientific, among other device companies, began to modify the mesh used in hernia repair to be used as products specifically intended to correct pelvic organ prolapse and/or SUI. Boston Scientific sold pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Pelvic Mesh Products manufactured by Boston Scientific are regulated by the U.S. Food and Drug Administration (FDA) and until 2016 were considered Class II medical devices.[1,2]

20. Defendant sought and obtained FDA clearance to market the Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices in commercial distribution prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever

[1] In 2016, the FDA reclassified surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse as Class III (high risk) medical devices.
[2] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants.

conducted by Boston Scientific with regard to the Pelvic Mesh Devices prior to placing them on the market.

21. Between approximately 2005 and 2007, the Food and Drug Administration (FDA), received reports of over 1,000 adverse events associated with transvaginally placed mesh devices.

22. Between approximately 2008 and 2010, the FDA received over 2,800 reports of adverse events involving individuals who had transvaginally placed mesh devices. The reported complications from these devices included, but were not limited to, mesh erosion through the vagina, pain, infection, bleeding, dyspareunia, organ perforation and urinary problems. Many of these complications required additional extensive surgical intervention and treatment.

23. Defendant's Obtryx Halo device contains monofilament polypropylene mesh and was designed and intended to be permanently implanted into the human body. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the Plaintiff is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the devices. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

24. Boston Scientific used Marlex® HGX-030-01 Polypropylene Homopolymer resin in its transvaginal mesh kits, both pelvic organ prolapse kits and sling systems, including the Obtryx Halo Sling. The Marlex® resin was manufactured by Phillips Sumika Polypropylene Company, ("Phillips") a joint venture between Chevron Phillips Chemical Company, LP, and Sumitomo Chemical.

25. Marlex HGX-030-01 resin is a polypropylene plastic that comes in the form of pellets. For several years, Phillips issued revised Material Safety Data Sheets ("MSDS") for Marlex polypropylene. Boston Scientific was aware of the Marlex MSDS at all relevant times, including

when it manufactured and marketed its Pelvic Mesh Devices to the medical community, including Plaintiff's physicians.

26. The Marlex MSDS[3] expressly prohibits use of the material for permanent human implantation:

> "MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.
>
> DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL COMPANY LP MATERIAL IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM CHEVRON PHILLIPS CHEMICAL COMPANY LP UNDER AN AGREEMENT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.
>
> CHEVRON PHILLIPS CHEMICAL COMPANY LP MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THIS MATERIAL FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES."

27. On October 1, 2004, Phillips Sumika Polypropylene Company (PSPC) entered a one-year stand-alone indemnification/insurance agreement which waived the company's liability for Boston Scientific's decision to use the polypropylene material in medical applications. That agreement included the following language for Boston Scientific's use of the resin material in its transvaginal mesh products:

> BEFORE USING ANY PSPC POLYPROPYLENE PRODUCT, BOSTON SCIENTIFIC IS ADVISED AND CAUTIONED TO MAKE ITS OWN DETERMINATION AND ASSESSMENT OF THE SAFETY AND SUITABILITY OF THE PSPC POLYPROPYLENE PRODUCT FOR USE BY, FOR OR ON BEHALF OF BOSTON SCIENTIFIC. IT IS THE ULTIMATE RESPONSIBILITY OF BOSTON SCIENTIFIC TO ENSURE THAT THE PSPC POLYPROPYLENE PRODUCT IS SUITED TO BOSTON SCIENTIFIC'S SPECIFIC APPLICATION.

[3] A true and correct copy of the Material Safety Data Sheet for Marlex® Polypropylene (All Grades) is attached hereto as Ex. A.

28. The 2004 Indemnity Agreement placed the burden on Boston Scientific to conduct any and all necessary testing to ensure that the product they marketed with Marlex resin was safe for its intended use.

29. Boston Scientific performed no long-term safety studies on the dangers associated with the permanent implantation of its Pelvic Mesh Devices, including the Obtryx Halo Sling.

30. Subsequent to this 2004 indemnity agreement, in September of 2005, Phillips decided not to renew its contract with Boston Scientific, because the resin was not intended for use in permanent implant devices. Per the terms of the 2004 contract between the two companies, Boston Scientific decided to exercise a right it held to make a "last-time" buyout before the contract was terminated. In 2005, Boston Scientific purchased 4,000 pounds of Marlex® HGX-030-01, the equivalent of a 10-year supply.

31. Synthetic materials like polypropylene are known to induce an acute inflammatory response, followed by chronic inflammatory response and foreign-body reaction. A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the patient. Further, a prolonged inflammatory response exposes the polypropylene mesh to a continuous bath of oxidants that may cause in vivo degradation of the mesh. Notably, the polypropylene MSDS specifies that polypropylene may react with strong oxidizing agents. Despite the known warnings and complications, Boston Scientific utilized Marlex that had never been qualified by the supplier for permanent human implantation for a medical application that was disallowed according to the Material Safety Data Sheet (MSDS) in its manufacture of the Obtryx sling.

32. The polypropylene mesh used by Boston Scientific for its Obtryx Halo sling also contracts as a result of the development of scar tissue exacerbated by the foreign body reaction.

Polypropylene mesh is known to shrink by up to over 50% during healing. When the transvaginal mesh shrinks during the normal healing process, the arms of the mesh pull on their anchoring points in the pelvic sidewall muscles, tending to pull these anchoring points and the attached muscle toward the midline. In women with these transvaginal mesh implants, including Plaintiff herein, this pulling on the pelvic sidewall muscles causes pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping and straining. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. In addition, it is well established that nerves can become entrapped as a result of the chronic inflammatory response and fibrosis surrounding the mesh.

33. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in Defendant's Pelvic Mesh Products) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

VII. PLAINTIFF'S INJURIES

34. On March 23, 2018, Ms. Margowski underwent surgery for pelvic pain, dyspareunia, and stress urinary incontinence with the aim of curing these problems.

35. During the surgery, her surgeon, Dr. Mark K. Widstrom, performed a laparoscopic salpingectomy, lysis of adhesions, cystoscopy, and implanted the Obtryx Halo sling, using the Obtryx halo needles, which were passed through incisions, through the obturator muscle, and membrane, pulling the tape back through bilaterally. The operative note does not demonstrate any deviations from the Obtryx Halo product instructions provided by Boston Scientific.

36. On February 20, 2020 Ms. Margowski was seen for perineal and buttock pain and heavy vaginal discharge. It was discussed that her pain could be due to mesh and would be referred to Rochester for further evaluation.

37. On April 28, 2020 Ms. Margowski presented to Mayo and was diagnosed with suburethral mesh erosion. It was determined that this was likely causing her bacterial vaginosis symptoms and significantly contributing to her pain.

38. On August 19, 2020 Ms. Margowski underwent an excision of the suburethral portion of trans obturator midurethral sling and a cystoscopy by Dr. John Occhino. Right and left periurethral mesh erosion was noted on bimanual examination. Ms. Margowski's post operative diagnosis was dysfunction suburethral mesh sling, suburethral mesh erosion, pelvic pain, and recurrent vaginal infections.

39. Ms. Margowski was seen on November 2, 2020 by Dr. Derek Beyer and reported that she was having issues with urinary urgency and had pain during intercourse.

40. Following this procedure, Ms. Margowski continued to experience severe pain associated with the most basic of activities, such as sitting, among other things. This pain continues to this day.

41. Ms. Margowski has also attended physical therapy sessions to control the pain.

42. These injuries were specifically caused by the defective warnings provided to Dr. Widstrom and design of the Obtryx Halo device, and specifically (but not limited to) deficient pore size, material mismatch, loss of elasticity, severe shrinkage and contraction, chronic inflammatory properties and the placement of the mesh into the obturator muscles.

43. The Boston Scientific DFU failed to warn of the very complications experienced by Tonya Margowski, including chronic, uncurable pelvic pain, vaginal pain, sitting pain, buttock pain, chronic dyspareunia, the increased risk of recurrent stress incontinence, the increased risk of requiring additional surgeries, and the increased risk of de novo urgency and frequency associated with the Obtryx Halo sling.

44. Upon information and belief, Dr. Widstrom relied upon the information and warning from Boston Scientific in making the decision to implant the Obtryx Halo sling in Tonya Margowski and in obtaining her consent to undergo the procedure.

45. Boston Scientific's failure to accurately disclose the true risks of its Obtryx Halo sling were a proximate cause of Tonya Margowski's injuries.

46. As a result of having the Obtryx Halo sling implanted in her, Tonya Margowski has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

VIII. PLAINTIFF'S RESULTING DAMAGES AND INJURIES

47. Plaintiff suffered serious personal injuries as a direct and proximate result of the Defendant's failure to provide adequate warnings, failure to design, manufacture, sell, or distribute a safe product, and failure to adhere to safe manufacturing processes.

48. As a direct and proximate result of these Defendant's wrongful conduct and the use of Defendant's defective device, Plaintiff suffered and will continue to suffer from severe injuries and damages, including but not limited to severe personal injuries, great emotional distress, and mental anguish.

49. As a result of use of the Obtryx Halo sling as designed, manufactured, promoted, sold and/or supplied by Boston Scientific, and as a result of the negligence, callousness and the other wrongdoing and misconduct of the Defendant as described herein:

a. Plaintiff was injured and suffered injuries to Plaintiff's body and mind, the exact extent of which is not completely known to date;

b. Plaintiff sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

c. Plaintiff incurred medical expenses and will be required to incur additional medical expenses in the future as a result of the injuries and damages Plaintiff suffered;

d. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interests thereon and costs.

IX. CAUSES OF ACTION

COUNT I: STRICT LIABILITY

A. Design Defect Allegations

50. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

51. Prior to, on, and after the date the Device (the subject Obtryx Halo Sling) was implanted in Plaintiff Tonya Margowski and at all relevant times, Defendant designed, distributed, manufactured, sold, and marketed the Obtryx Halo sling for use in the United States, including Minnesota.

52. At all times herein mentioned, Defendant designed, distributed, manufactured, marketed, and sold the Obtryx Halo sling such that it was dangerous, unsafe, and defective due to design, manufacture, and lack of adequate warnings.

53. The Obtryx Halo sling was in a condition unreasonably dangerous to users like Tonya Margowski.

54. The Obtryx Halo sling contained all of the defects alleged herein at the time it left Boston Scientific's possession and reached Plaintiff Tonya Margowski without substantial change in the condition in which it was sold.

55. The Obtryx Halo sling had potential risks and side effects that were known or knowable to Defendant by the use of scientific knowledge available before, at, and after the manufacture, distribution, and sale of the Obtryx Halo sling.

56. Defendant knew or should have known of the defective condition, characteristics, and risks associated with the Obtryx Halo sling, as previously set forth herein.

57. The Product implanted in Plaintiff Tonya Margowski was not reasonably safe for its intended uses and was defective as described herein with respect to its design. Said design defects include, but are not limited to:

a. The use of polypropylene material in the Device and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Device to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Device, including, but not limited to, the propensity of the Device to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Device which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Device for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

f. The hyper-inflammatory responses to the polypropylene Device leading to problems including chronic pain and fibrotic reaction;

g. The propensity of the polypropylene Device to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

h. The adverse tissue reactions caused by polypropylene Device, which are causally related to infection, as polypropylene is a foreign organic material from animals and/or human cadavers;

i. The harshness of the polypropylene Device upon the female pelvic tissue, and the hardening of the Device in the body;

j. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions;

k. The Obtryx Halo device uses a permanent anchoring head, also made of polypropylene that is placed blindly through the obturator membrane into the obturator foramen. Within the obturator foramen lie numerous muscles including the obturator internus, obturator and pudendal nerves, and vascular structures. Despite Boston Scientific Corporation promoting and marketing the Obtryx Halo device as a less invasive device than other mesh devices used for the treatment of stress urinary incontinence, Boston Scientific did not perform any tests or studies on the Obtryx Halo product prior to marketing the device. Moreover, Boston Scientific Corporation knew there were increased risks with the blind placement of the Obtryx Halo through the obturator membrane and into the obturator foramen, but failed to inform physicians or patients about the foreseeable and unavoidable risks of injury to vascular structures, muscles and nerves both acutely and over-time.

l. Boston Scientific Corporation further knew of the risk that the permanent anchoring heads utilized by the Obtryx Halo device into the obturator membrane and foramen would make the attempted removal of the mesh, and the permanent anchoring heads, very difficult. Despite knowing of this increased risk, Boston Scientific Corporation

failed to inform physicians and patients and moved forward with marketing the device and implanting the device into thousands of women, including Tonya Margowski; and

m. The use of polypropylene material in the Obtryx Halo sling and anchors and the failure to provide adequate directions for use (DFU) and physician training.

58. At the time Plaintiff Tonya Margowski underwent surgery to have the Obtryx Halo sling implanted, technologically feasible alternatives existed, including the use of sutures, such as delayed absorbable sutures like PDS, in a colposuspension procedure like the Burch; autologous fascia slings; allograft slings such as Repliform; slings with less polypropylene such as Ultrapro; and a retropubic sling that does not pass to or through the obturator membrane. These safer alternative designs were capable of eliminating or significantly reducing Tonya Margowski's injuries, which would not have occurred but for the use of the Obtryx Halo sling, that were a result of the specific design flaws of the Obtryx Halo sling, including degradation, stiffness, migration, deformation, fraying, roping, cording, curling, banding, scarring, shrinkage/contraction, scar plate formation, chronic inflammation, chronic foreign body reaction, loss of pore size with tension, dense, heavy, and frayed, rough edges, and blind placement of the arms through the obturator foramen.

59. At the time Plaintiff Tonya Margowski underwent surgery to have the Obtryx Halo sling implanted, Defendant knew but failed to inform Plaintiff or her implanting physician that the risks of using the device outweighed its benefits.

60. Upon information and belief, had Tonya Margowski's implanting physician been aware of the true risks of using the Obtryx Halo sling, he would not have prescribed it or implanted it into Tonya Margowski.

61. Had Tonya Margowski been aware of the true risks of using the Obtryx Halo sling, she would not have consented to having it implanted.

62. As a direct and proximate result of the Obtryx Halo Sling's design defects as described hereinabove, Tonya Margowski has developed complications, as described above, as a result of the Obtryx Halo sling being implanted in her body, causing chronic inflammation, foreign body reaction, scarring, contraction, shrinkage, deformation and degradation of the mesh due to the defects of the Obtryx Halo sling mesh, and defects related to the procedure in placement as described above.

63. Plaintiff Tonya Margowski has been catastrophically injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, humiliation, disfigurement, loss of care, comfort, and economic damages.

64. Thus, Defendant is strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling defective Products.

B. Failure to Warn Allegations

65. Prior to, on, and after the date the Device was implanted in Plaintiff Tonya Margowski, and at all relevant times, Defendant designed, tested, distributed, manufactured, advertised, sold, and marketed the Pelvic Mesh Device for use by consumers, such as Plaintiff, in the United States.

66. Prior to the time the Obtryx Halo sling was implanted in Ms. Tonya Margowski, Boston Scientific had reason to know of the dangers of using the Obtryx Halo sling.

67. Prior to, on, and after the date the Device was implanted in Plaintiff Tonya Margowski, Defendant had a duty to exercise due care and avoid unreasonable risk of harm in and about their design, developing, assembling, licensing, labeling, testing, distributing, manufacturing, supplying, ordering, advertising, selling, and marketing of the transvaginal mesh device implanted into the Plaintiff, including the duty to assure that the product did not pose a significantly increased risk of bodily harm and adverse events.

68. The Device implanted in Tonya Margowski, the Obtryx Halo sling, was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Boston Scientific breached its duty of care and did not provide sufficient or adequate warnings to Ms. Tonya Margowski and Plaintiff's implanting physicians regarding, among other subjects:

a. The Device's propensities to contract, retract, and/or shrink inside the body;

b. The Device's propensities for degradation, fragmentation, migration, and/or disintegration;

c. The Obtryx Halo's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Device;

f. The risk of chronic infections resulting from the Device;

g. The risk of permanent vaginal or pelvic scarring as a result of the Device;

h. The risk of de novo urinary dysfunction;

i. The risk of recurrent, intractable, permanent pelvic pain and other pain resulting from the Obtryx Halo;

j. The need for corrective or revision surgery to adjust or remove the Obtryx Halo, which is some cases I not feasible or possible;

k. The severity of complications that could arise as a result of implantation of the Obtryx Halo;

l. The hazards associated with the Obtryx Halo;

m. The Obtryx Halo's defects described herein;

n. Treatment of stress urinary incontinence with the Obtryx Halo is no more effective than feasible available alternatives;

o. Treatment of stress urinary incontinence with the Obtryx Halo exposes patients to greater risk than feasible available alternatives;

p. Treatment of stress urinary incontinence with the Obtryx Halo makes future surgical repair more difficult than feasible available alternatives;

q. Use of the Obtryx Halo puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

r. Removal of the Obtryx Halo due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

s. Complete removal of the Obtryx Halo may not be possible and may not result in complete resolution of the complications, including pain; and

t. The nature, magnitude and frequency of complications that could arise as a result of implantation of the Obtryx Halo.

69. Upon information and belief, had Ms. Tonya Margowski's implanting physician been aware of the true risks of using the Obtryx Halo sling, he would not have prescribed it or implanted it into Ms. Tonya Margowski.

70. Had Ms. Tonya Margowski been aware of the true risks of using the Obtryx Halo sling, she would not have consented to having it implanted.

C. Causation and Damages

71. As a direct and proximate result of the defects and failure to provide adequate warnings as described herein, Plaintiff Tonya Margowski has been catastrophically injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, humiliation, disfigurement, loss of care, comfort, and economic damages.

COUNT II: NEGLIGENCE

72. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

73. Prior to, on, and after the date of Plaintiff's implantation with the Obtryx Halo, and at all relevant times, Defendant designed, distributed, manufactured, sold, and marketed the Obtryx Halo for use by consumers such as Plaintiff in the United States.

74. Prior to, on, and after the date of Plaintiff's implantation with the Obtryx Halo, and at all relevant times, Defendant knew or reasonably should have known that the Obtryx Halo and its warnings were dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

75. Prior to, on, and after the date of Plaintiff's implantation with the Obtryx Halo, and at all relevant times, Defendant became aware that the defects of the Obtryx Halo resulted in the Obtryx Halo causing injuries similar to those Plaintiff Tonya Margowski suffered.

76. Prior to and on the date of Plaintiff's implantation with the Obtryx Halo, Defendant breached its duty of care owed to Plaintiff Tonya Margowski and her physicians by its actions and inactions, including but not limited to the following:

a. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care to warn Plaintiff's treating physicians about the Device's substantially dangerous condition or about facts making the product likely to be dangerous;

d. Negligently recruiting and training physicians and surgeons to implant its Pelvic Mesh Products and without adequately providing information about the severity frequency and permanency of the risks to those physicians and surgeons;

e. Failing to perform reasonable pre- and post-market testing of the Device to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Device;

g. Advertising, marketing, and recommending the use of the Device, while concealing and failing to disclose or to warn of the dangers known by Defendant to be connected with and inherent in the use of the Device;

h. Representing that the Device was safe for its intended use when, in fact, Defendant knew or should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Device without disclosing that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations and policy;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Device so as to avoid the risk of serious harm associated with the use of the Device; and

k. Failing to perform adequate evaluation and testing of the Device where such evaluation and testing would have revealed the propensity of the Device to cause injuries as described herein.

77. As a direct and proximate result of Defendant's negligence, as set forth herein, Plaintiff Tonya Margowski has been catastrophically injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, humiliation, disfigurement, loss of care, comfort, and economic damages.

COUNT III: BREACH OF EXPRESS WARRANTY

78. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

79. At all material times hereto, Defendant manufactured, distributed, advertised, promoted, and/or sold its pelvic mesh products, including the Obtryx Halo implanted into Plaintiff Tonya Margowski.

80. At all material times hereto, Defendant intended its Obtryx Halo to be used in the manner used by Plaintiff Tonya Margowski.

81. At all material times hereto, Defendant expressly warranted that its Pelvic Mesh Products, including the Obtryx Halo, were safe and fit for use by consumers, that these products were of merchantable quality, that their effects were minimal and comparable to other treatments for SUI and/or POP, and that they were adequately tested and fit for their intended use.

82. Boston Scientific further warranted that the Obtryx Halo sling would function effectively in that it would alleviate Ms. Tonya Margowski's stress urinary incontinence and that using the SUI for this type of treatment was safe.

83. At all material times hereto, Defendant was aware that consumers, including Plaintiff Tonya Margowski, would use its Pelvic Mesh Products, including the Obtryx Halo, and accordingly, that Plaintiff Tonya Margowski, was a foreseeable user of its Pelvic Mesh Products.

84. Defendant's Pelvic Mesh Products were expected to reach, and did in fact reach, the ultimate consumer, Plaintiff Tonya Margowski and her implanting physicians, without substantial change in the condition in which they were manufactured and sold by Defendant.

85. Defendant breached express warranties with respect to its Pelvic Mesh Products, including the following:

a. By representing to Plaintiff Tonya Margowski and her healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that its Pelvic Mesh Products, including the Obtryx Halo, were safe, while withholding and concealing information about the substantial risks of serious injury associated with its Pelvic Mesh Products[4];

b. By representing to Plaintiff Tonya Margowski and her healthcare providers that its Pelvic Mesh Products, including the Obtryx Halo, were as safe, and/or safer than other alternative procedures and devices, while withholding and concealing information that demonstrated its Pelvic Mesh Products were less safe than alternatives available on the market; and

[4] These representations touted surgical mesh implantation as a quick, easy, and minimally invasive procedure while misrepresenting, concealing, and minimizing the associated complications and other facts needed to accurately weigh risks versus benefits of surgical mesh products. Boston Scientific continues to this day to espouse the safety of its Pelvic Mesh Devices directly to consumers, physicians and patients throughout the country, including in Minnesota, via its websites and other direct marketing materials. *See*, e.g., www.pelvic-floor-institute.com; www.supporting-women.com; https://www.voicesforpfd.org/; https://www.voicesforpfd.org/ (formerly known as supportingwomen.com); https://www.chooseyou.com/home.html.

c. By representing to Plaintiff Tonya Margowski and her healthcare providers that its Pelvic Mesh Products, including the Obtryx Halo, were more efficacious than other alternative medications, while withholding and concealing information regarding the true efficacy of its Pelvic Mesh Products.

86. In reliance upon Defendant's express warranties, Plaintiff Tonya Margowski was implanted with Defendant's Device, as prescribed and directed; and, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

87. At the time of making such express warranties, Defendant knew or should have known that its Pelvic Mesh Products did not conform to these express warranties because they were not safe and had numerous serious side effects, many of which Defendant did not accurately warn about, thus making them unreasonably unsafe for their intended purpose.

88. The public, the medical community, Plaintiff Tonya Margowski and her physicians, relied on Defendant's representations and express warranties in connection with the use, recommendation, description, and dispensing of its Pelvic Mesh Products, including the Device implanted into Plaintiff Tonya Margowski.

89. Defendant breached its express warranty to Plaintiff Tonya Margowski in that its Device was not of merchantable quality, safe and fit for its intended use, nor was it adequately tested.

90. The failure of Defendant's Device to be as expressly warranted was a substantial factor in causing Plaintiff Tonya Margowski's injuries as described herein.

91. As a direct and proximate result of Defendant's breach of express warranty, Plaintiff Tonya Margowski has been catastrophically injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, humiliation, disfigurement, loss of care, comfort, and economic damages.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for relief and demands judgment against Defendant at trial and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B. For general damages in a sum exceeding this Court's jurisdictional minimum;

C. For specific damages according to proof;

D. For all ascertainable economic and non-economic damages according to proof in a sum exceeding this Court's jurisdictional minimum;

E. For restitution and disgorgement of profits;

F. For Attorneys' fees;

G. For pre-judgment interest and post-judgment interest as allowed by law;

H. The costs of these proceedings; and

I. For such other and further relief as this Court deems just and proper or which is permitted under the law.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

Respectfully submitted,

GOLDENBERGLAW, PLLC

Dated: January 20th, 2022

By: *s/ Marlene J. Goldenberg*
Marlene J. Goldenberg (MN Bar #0394943)

Stuart L. Goldenberg (MN Bar #158719)
800 LaSalle Avenue, Suite 2150
Minneapolis MN 55402
(612) 436-5028 (Direct)
(612) 367-8107 (Fax)
mjgoldenberg@goldenberglaw.com
slgoldenberg@goldenberglaw.com